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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,959	02/25/2004	William Toreki	QMT1.1-CIP2-US	4101
3775	7590	03/04/2009	EXAMINER	
ELMAN TECHNOLOGY LAW, P.C. P. O. BOX 209 SWARTHMORE, PA 19081			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
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			03/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,959	TOREKI ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 December 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 60,61,64-68 and 70-72 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 60,61,64-68 and 70-72 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/2008</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 61 is rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. (US 5,575,993), for the reasons set forth in the previous office action filed 03/06/2008.

Applicant's arguments filed 12/12/2008 have been fully considered but they are not persuasive. Applicants assert that as amended Ward cannot anticipate their claims due to the new recitation that the polyionic polymer is non-leachably bound to the substrate and Ward specifically mentions that the polymers are washed off during washing procedures.

The examiner respectfully disagrees. Firstly it is noted that applicants passages within their own specification ([0066]-[0067]) states that non-leachably means that sections of the polymer of the invention do not appreciably separate from the material and enter a wound or otherwise become non-integral with the material under standard uses. The examiner considers the normal use of a bandage as in Ward is wound treatment, just because the polymers may be washed off after their used as a wound bandage does not differentiate applicants claimed invention from that of Ward. The normal use of a bandage is to treat wounds, since the bandage of Ward performs the normal use of a wound bandage, non-leachably attached does not exclude the

composition of Ward in which the polymers may be washed off from the gauze if desired. It is further noted by the examiner that since the composition of Ward is within applicants claimed scope it will inherently have the same properties including the bonding strength of the polymer to substrate. Applicants have not amended their broadest claim 60 in such a way to exclude the bandage of Ward.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 61 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828) in view of Ward et al. (US 5,575,993), for the reasons set forth in the previous office action filed 03/06/2008.

As in the arguments above applicants assert that their new limitation that the polymer is non-leachable would preclude the Ward reference and further states that it effectively teaches away from their claimed invention.

For the reasons cited above the examiner does not believe the Ward reference is excluded by applicants new limitations nor would it teach away from the claimed features.

Applicants further assert that since Batich discloses cationic polymers that are non-leachably bound to the substrate there would be no expectation of success for one of ordinary skill in the art to combine such a teaching with Ward who discloses polymers that are readily washed away. Applicants also surmise that the combination would not teach how one could obtain a biologically active anionic species associated with a

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quaternary ammonium polymer that is non-leachable. Applicants also assert that there would be no reason to combine the two references since they both describe opposite concepts in that Batich the polymers are not readily absorbed in aqueous solutions while the polymers of Ward can be washed off.

As noted in previous office actions Ward was used as a secondary reference for its disclosure that it was already known in the art that anionic antimicrobial compounds could be associated to cationic polymers. Since Batich describes cationic polymers that as applicants purport are non-leachable and Ward teaches that cationic polymers were well known to be capable of releasing anionic drugs, applicant's claimed method of treatment comprising applying a cationic polymer with an ionically associated with an antimicrobial could have been obvious. As detailed above applicants assertion that the polymer is bound to a substrate material does not preclude the Ward reference from reading on their claims.

Claims 60,64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828) in view of Schoenfeldt et al. (US 2002/0172708) and in further view of Voorhees et al. (US 2004/0235950 A1), for the reasons set forth in the previous office action filed 03/06/2008.

Applicant's arguments have been fully considered but they are not persuasive. Applicants assert as previously argued that Batich does not teach an MMP active ingredient that is ionically associated with a quaternary ammonium polymer. Applicants assert that Schoenfeldt does not suggest a process where quaternary ammonium polymers or copolymers are components of polyionic polymers. Applicants also assert

that Schoenfeldt does not suggest a process where the sol gel is bound to a substrate. Applicant's further state that Schoenfeldt does not teach a cationic polymer backbone comprised of quaternary ammonium groups and teaches away from ammonium copolymers because the reference recites the best results are achieved with primary amines. Applicants lastly assert that Voorhees does not suggest binding their compositions in conjunction with an insoluble substrate.

The examiner respectfully disagrees with the above assertions by applicants. The examiner noted in previous office actions that Batich does not disclose ionic association of active drugs with the ammonium polymer, which is why it was combined with the Schoenfeldt reference. If Batich did disclose anionic MMP's in association with the cationic polymer the reference would be an anticipatory reference on its own merit, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As detailed in previous actions Schoenfeldt was used as a secondary reference for its disclosure on ionic association of MMP and cationic polymers. Since Ward and Voorhees are used as secondary references they do not have to disclose all of applicants claimed limitations on their own merit. Regarding applicant's assertion that Schoenfeldt does not describe a cationic polymer backbone comprised of quaternary ammonium groups, which is different than their own claimed invention, as noted above Schoenfeldt was used as a secondary reference and does not have to recite all of applicants claimed features on its own merit. Schoenfeldt does clearly recite that the

polyionic polymer contains at least one cationic group which includes amines, a cationic amine is an ammonium ion (which includes protonated substituted amines), and these polymers can incorporate the claimed ilomastat active ingredient. Disclosing cationic amine hardly teaches away from quaternary ammonium ions since they are similar functional groups, differing only in the number of substituted alkyl groups on the amine nitrogen. Thus the examiner concludes that since the polymers of Schoenfeldt and Batich are at least related as ammonium containing polymers, one of ordinary skill in the art would have a reasonable expectation of success in combining the references to make a quaternary ammonium polymer containing ilomastat.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618